Interview Summary	Application No.	Applicant(s)
	09/682,249	GRUNE, GUERRY L.
	Examin r	Art Unit
	Marina Lamm	1616
All participants (applicant, applicant's representative, PTO personnel):		
(1) <u>Marina Lamm</u> .	(3)	
(2) <u>GRUNE, GUERRY L.</u> .	(4)	•
Date of Interview: <u>17 July 2002</u> .		
Type: a)☐ Telephonic b)☐ Video Conference c)⊠ Personal [copy given to: 1)⊠ applicant 2	2)☐ applicant's represer	ntative]
Exhibit shown or demonstration conducted: d)⊠ Yes If Yes, brief description: sample of the inventive compo	e)⊡ No. sition	
Claim(s) discussed: <u>all</u> .	·	
Identification of prior art discussed: art of record.	•	·
Agreement with respect to the claims f) was reached.	g) was not reached.	h) N/A.
Substance of Interview including description of the general reached, or any other comments: <u>discussed all outstanding</u> (A fuller description, if necessary, and a copy of the amendral outstanding allowable, if available, must be attached.	rejections and possible a	amendments to the claims .
allowable, if available, must be attached. Also, where no co allowable is available, a summary thereof must be attached	ppy of the amendments th .)	at would render the claims
 i) It is not necessary for applicant to provide a sep checked). 	parate record of the subst	ance of the interview(if box is
Unless the paragraph above has been checked, THE FORM MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. action has already been filed, APPLICANT IS GIVEN ONE METATEMENT OF THE SUBSTANCE OF THE INTERVIEW. reverse side or on attached sheet.	(See MPEP Section 713) MONTH FROM THIS INT	.04). If a reply to the last Office
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Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.	_//_	
and of the district of a signed office action.	⊢xaminer's si	gnature, if required

U.S. Patent and Trademark Office PTO-413 (Rev. 03- 98)

Examiner's signature, if required

Summary of Record of Interview Requirements

Manual of Patent Examining Procedure (MPEP), Section 713.04, Substance of Interview Must be Made of Record

A complete written statement as to the substance of any face-to-face, video conference, or telephone interview with regard to an application must be made of record in the application whether or not an agreement with the examiner was reached at the interview.

Title 37 Code of Federal Regulations (CFR) § 1.133 Interviews

Paragraph (b)

In every instance where reconsideration is requested in view of an interview with an examiner, a complete written statement of the reasons presented at the interview as warranting favorable action must be filed by the applicant. An interview does not remove the necessity for reply to Office action as specified in §§ 1.111, 1.135. (35 U.S.C. 132)

37 CFR §1.2 Business to be transacted in writing.

All business with the Patent or Trademark Office should be transacted in writing. The personal attendance of applicants or their attorneys or agents at the Patent and Trademark Office is unnecessary. The action of the Patent and Trademark Office will be based exclusively on the written record in the Office. No attention will be paid to any alleged oral promise, stipulation, or understanding in relation to which there is disagreement or doubt.

The action of the Patent and Trademark Office cannot be based exclusively on the written record in the Office if that record is itself incomplete through the failure to record the substance of interviews.

It is the responsibility of the applicant or the attorney or agent to make the substance of an interview of record in the application file, unless the examiner indicates he or she will do so. It is the examiner's responsibility to see that such a record is made and to correct material inaccuracies which bear directly on the question of patentability.

Examiners must complete an Interview Summary Form for each interview held where a matter of substance has been discussed during the interview by checking the appropriate boxes and filling in the blanks. Discussions regarding only procedural matters, directed solely to restriction requirements for which interview recordation is otherwise provided for in Section 812.01 of the Manual of Patent Examining Procedure, or pointing out typographical errors or unreadable script in Office actions or the like, are excluded from the interview recordation procedures below. Where the substance of an interview is completely recorded in an Examiners Amendment, no separate Interview Summary Record is required.

The Interview Summary Form shall be given an appropriate Paper No., placed in the right hand portion of the file, and listed on the "Contents" section of the file wrapper. In a personal interview, a duplicate of the Form is given to the applicant (or attorney or agent) at the conclusion of the interview. In the case of a telephone or video-conference interview, the copy is mailed to the applicant's correspondence address either with or prior to the next official communication. If additional correspondence from the examiner is not likely before an allowance or if other circumstances dictate, the Form should be mailed promptly after the interview rather than with the next official communication.

The Form provides for recordation of the following information:

- Application Number (Series Code and Serial Number)
- Name of applicant
- Name of examiner
- Date of interview
- Type of interview (telephonic, video-conference, or personal)
- Name of participant(s) (applicant, attorney or agent, examiner, other PTO personnel, etc.)
- An indication whether or not an exhibit was shown or a demonstration conducted
- An identification of the specific prior art discussed
- An indication whether an agreement was reached and if so, a description of the general nature of the agreement (may be by attachment of a copy of amendments or claims agreed as being allowable). Note: Agreement as to allowability is tentative and does not restrict further action by the examiner to the contrary.
- The signature of the examiner who conducted the interview (if Form is not an attachment to a signed Office action)

It is desirable that the examiner orally remind the applicant of his or her obligation to record the substance of the interview of each case unless both applicant and examiner agree that the examiner will record same. Where the examiner agrees to record the substance of the interview, or when it is adequately recorded on the Form or in an attachment to the Form, the examiner should check the appropriate box at the bottom of the Form which informs the applicant that the submission of a separate record of the substance of the interview as a supplement to the Form is not required.

It should be noted, however, that the Interview Summary Form will not normally be considered a complete and proper recordation of the interview unless it includes, or is supplemented by the applicant or the examiner to include, all of the applicable items required below concerning the substance of the interview.

A complete and proper recordation of the substance of any interview should include at least the following applicable items:

- 1) A brief description of the nature of any exhibit shown or any demonstration conducted,
- 2) an identification of the claims discussed,
- 3) an identification of the specific prior art discussed,
- 4) an identification of the principal proposed amendments of a substantive nature discussed, unless these are already described on the Interview Summary Form completed by the Examiner,
- 5) a brief identification of the general thrust of the principal arguments presented to the examiner,
 - (The identification of arguments need not be lengthy or elaborate. A verbatim or highly detailed description of the arguments is not required. The identification of the arguments is sufficient if the general nature or thrust of the principal arguments made to the examiner can be understood in the context of the application file. Of course, the applicant may desire to emphasize and fully describe those arguments which he or she feels were or might be persuasive to the examiner.)
- 6) a general indication of any other pertinent matters discussed, and
- 7) if appropriate, the general results or outcome of the interview unless already described in the Interview Summary Form completed by the examiner.

Examiners are expected to carefully review the applicant's record of the substance of an interview. If the record is not complete and accurate, the examiner will give the applicant an extendable one month time period to correct the record.

Examiner to Check for Accuracy

If the claims are allowable for other reasons of record, the examiner should send a letter setting forth the examiner's version of the statement attributed to him or her. If the record is complete and accurate, the examiner should place the indication, "Interview Record OK" on the paper recording the substance of the interview along with the date and the examiner's initials.

STATEMENT OF THE SUBSTANCE OF THE INTERVIEW: (Optional)

Submitted August 9, 2002

Application Number: 09/682,249

Title: NON-ENDOCRINE DISRUPTING CYTOPROTECTIVE UV RADIATION RESISTANT

COMPOSITION

Name of Applicant: Guerry L. Grune Name of Examiner: Marina Lamm Date of Interview: July 17, 2002 Type of Interview: Personal

Name of Participants: Applicant (who is also Agent) and Examiner Only

Exhibit was shown (actually 2)

Identification of the specific prior art discussed (see below)

General Agreement was reached (based on discussion with examiner as stated and documented and

memorialized below)

Examiner signed the Interview Summary

Summary of the 7/17/02 interview regarding USP Application Number 09/682,249 with examiner Marina Lamm;

Patent practitioner and inventor Guerry L. Grune met with Examiner Lamm from 1:00 PM – 2:10 PM in her office at the USPTO to discuss the 1st Office Action objections and rejections regarding USP application number 09/682,249. The interview started by G. Grune giving examiner Lamm 2 samples of the sunblock which were representative of the invention.

Next, G. Grune requested (and Ms. Lamm agreed) to go through the Office Action in a step-by-step orderly fashion. This was accomplished as follows;

G. Grune did not try to reargue the Restriction requirement by Ms. Lamm. Therefore the interview was directed only to the Office Action dated 2/28/2002.

G. Grune understood the objection under 37 USC 1.75 (c) regarding improper claim form for claims 26 and 27. G. Grune stated that he would omit the word "and" and insert the word "or". Examiner Lamm agreed that this would be persuasive but only if claims 12, 23, and 24 were cancelled due as required by the Election after the Restriction

Examiner Lamm explained that a divisional can be filed to copend with the parent application. The non-elected claims would then be canceled by Preliminary Amendment and prosecution of this separate application could proceed.

Claim 25 was not discussed, but it will be amended or cancelled as necessary to overcome the 35 USC 101 Double Patenting rejection.

Next, G. Grune explained the inventive concept and how claim 1 and all subsequent claims dependent on claim 1 were enabling to one skilled in the art. G. Grune explained that in addition to the article referenced in the specification to Margeret Schlumpf, a list of known or suspected endocrines is on a website posted by EPA, so that "one skilled in

the art" would immediately understand and recognize the differences between endocrine disruptive substances and those that are non-endocrine disruptive. Examiner Lamm understood and stated that the phrase "wherein the non-endocrine disruptive components..." should be inserted into the claims where non-endocrine disrupting agents are required. Ms. Lamm stated that it was of utmost importance to show where there was support for these claims in the specification (and these were shown – on page 1, lines 18-22 of page 10, lines 42-44 of page 11, etc of the applicant's copy of the specification). Ms. Lamm added that because the prior art has both endocrine and non-endocrine disrupting agents, it must be made very clear how one "skilled in the art" would know which are which. Ms. Lamm stated that the EPA specific website address could be inserted in an IDS along with Margeret Schlumpf's article and it could be used as an exhibit in the rebuttal to the 35 USC 112 rejection.

Next came a discussion on the situation regarding indefiniteness. Basically, the inconsistency of using the words sunblock and sunscreen caused the examiner undue confusion and G. Grune apologized for the inconsistencies in the claim language. It was stated by G. Grune and agreed by Examiner Lamm that the composition was that of a sunblock, not a sunscreen and the amended claims must be consistent in that regard. Ms. Lamm understood that the antecedant basis rejection could be easily removed and that the language "consisting essentially of" might be helpful in overcoming any of the 35 USC 112 second paragraph rejections. Sunscreen compositions that are non-endocrine disrupting would only be claimed in accordance with the reference to butyl-methoxydibenzoylmethane and esters of the like as listed on page 10 of the applicant's copy of the application.

It was then explained, in great detail, that the invention is descriptive of a new composition, one which cannot be found on any retail shelves (Examiner Lamm told G. Grune she found sunblock using titanium dioxide or zinc oxide during her search) that is a combination of the following;

Cold pressed aloe – processing allows for retention of all cytoprotective agents in natural aloe

No known endocrine disrupters – well known to those "skilled in the art" Only titanium dioxide or zinc oxide as the sunblock agent – and only one known organic sunscreen agent could be used – that stated in the specification – and was pointed out to Examiner Lamm – on page 10 of applicant's copy – butyl-methoxydibenzoylmethane – because this substance has NOT been found to be an endocrine disrupter.

It was further explained to Examiner Lamm that based on documented effects with regard to endocrine disrupters (early onset of puberty in adolescents – particularly females, the hermophroditic insects, birds and fish that have been found in the environment, etc.), that there would most likely be a depressed immune system response in the presence of UV radiation and its already well documented harmful effect on mammalian skin. This response is unacceptable and more importantly unnecessary with the proper sunblock formulation which led to the present invention and the filing of this application.

Examiner Lamm stated that this composition must be clearly stated and defined in the claims. Ms. Lamm made it very clear that it was the inventor/agent's responsibility to show exactly where in the specification there is support for the claim(s) and that this showing of support together with the removal of the words "preferred" would overcome the 112 rejection.

Next, Ms. Lamm stated she was most concerned about the 102 rejections. Specifically it must be shown that the present invention has no known endocrine disrupters as she agreed that the cited patents; 5,980,871 and 5,972,362 and 5,824,659 do not make reference to endocrine disrupters or agents thereof. It is imperative that the inventor/agent show the specific differences in composition between the known prior art and the present invention. Again, Examiner Lamm stressed the need to show support from the specification and exactly where in the specification the support exists.

Examiner Lamm ended the interview with another review of the Wenker patent, USP 5,972,362, which indicates only one example of a sunscreen composition – that which includes the use of glycerin, titanium dioxide and an aloe vera gel. G. Grune indicated that the glycerin was not vegetable based, and Examiner Lamm stated that it was broad enough to include vegetable or non-vegetable based glycerin and would still offer a rejection based on that possibility. G. Grune then stated that the aloe was not "cold pressed" to which Examiner Lamm replied "is that important?" G. Grune stated it was of utmost importance because of the cytoprotective nature and qualities of the aloe if it is processed by what are currently very unconventional methods. Examiner Lamm understood, agreed, and stated that this needed to be explained in the response to overcome the rejections made under 102 and then again under 103.

It was also re-emphasized by G. Grune that there is no restriction regarding the use of only non-endocrine disrupting agents in the cited prior art or any other known art. Examiner Lamm understood and agreed to the proposed changes by amendment with the proviso that all amendments find support in the specification and are cited as to where they occur in the specification.

The interview ended at approximately 2:10 PM and then, at the request of G. Grune, to make the further and future examination proceed more smoothly, Examiner Lamm made a copy of her (electronically filed) version of the application so that G. Grune can point out specifically where the specification makes reference to what will become the amended claim(s) based on her office action of 2/28/02. G. Grune left Examiner Lamm's office at approximately 2:30 PM after thanking her for her time and for coming to the office specifically to meet with G. Grune while she is on maternity leave.